JAN 1 7 2003

K022035

## 9. 510 (k) Summary

Device Name: Osteomedics® Resorbable Small Fixation System, OsteoSorb®
Classification Name: Bone Plate, Bone Screw
Device Regulation Number:
Bone Plate: 76JEY (21 CFR 872.4760, 21 CFR 872.4880),

The Osteomedics® Resorbable Small Fixation System, OsteoSorb® consists of a series of plates, screws, bone fasteners and meshes, which are made from poly (L–lactide-co-D, L-lactide) 70: 30. The plates are designed in varying configurations and lengths, which are attached to the bone using screw or bone fastener fixation.

The Osteomedics® Resorbable Small Fixation System, OsteoSorb® is intended for use in selective trauma or for reconstructive procedures in the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin. The use is in both adult and pediatric patients cases involving trauma or reconstruction.

The substantial equivalence of device is based on similarities in intended use, design and operational principals to the Bionx® BiosorbFx® 1.5/2.0 Bioabsorbable Fixation System and the BiosorbFx® 2.0/2.4 Orthognathic / Mandibular Fix and Stryker Leibinger Wurzburg Titanium Mini Bone Plates and Bone Screws The material used in the manufacture of the Osteomedics® Resorbable Small Fixation System is poly (L–lactide-co-D, L-lactide) and is substantially equivalent to that used in the Bionx® Bioabsorbable Fixation System. The material used for Stryker Leibinger Wurzburg Titanium Mini Bone Plates and Bone Screws is Commercial Pure Titanium.

The basic operational principals, site preparation, relative indications and contraindications are similar for Osteomedics® Resorbable Small Fixation System and the, Bionx® Bioabsorbable Fixation System and Stryker Leibinger Wurzburg Titanium Mini Bone Plates and Bone Screws. This will provide stabilization and fixation of small bones of the craniofacial skeleton due to fracture or osteotomy.

**Official Contact Person:**

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6/18/2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2003

Mr. Albert Enayati
President
Osteomedics, Incorporated
809 Carter Lane
Paramus, New Jersey 07652

Re: K022035
Trade/Device Name: Osteomedics® Resorbable Small Fixation System, OsteoSorb®
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: October 28, 2002
Received: November 1, 2002

Dear Mr. Enayati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510 (k) Number ( if known):_____

Device Name: Osteomedics® Resorbable Small Fixation System, OsteoSorb®

Indications for use:

The Osteomedics® Resorbable Small Fixation System is intended for use in selective trauma or for reconstructive procedures in the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures, and selective orthognathic surgery of the maxilla and chin. The Osteomedics® Resorbable Small Fixation System stabilizes bone during healing in conjunction with appropriate postoperative immobilization. The use is in both adult and pediatric patients' cases involving trauma or reconstruction.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription use ✓ OR OVER – THE – COUNTER USE_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runge

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022035

6/18/2002